510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

OCT 2 1 2010

1. The submitter of this premarket notification is:

Andreas Suchi
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This summary was prepared on Oct 10, 2010.

2. The names of the devices are the Philips MP2, X2, MP5, MP5T, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90 and MX800 IntelliVue Patient Monitors
Classification names are as follows:

Device Panel	Classification	ProCode	Description
Cardiovascular Devices	§870.1025, II	DSI	Detector and alarm, arrhythmia
	§870.1025, II	MLD	Monitor, ST Segment with Alarm
	§870.1025, II	MHX	Monitor, Physiological, Patient (with arrhythmia detection or alarms)
	§870.1100, II	DSJ	Alarm, Blood Pressure
	§870.1110, II	DSK	Computer, Blood Pressure
	§870.1130, II	DXN	System, Measurement, Blood-Pressure, Non-Invasive
	§870.1435, II	DXG	Computer, Diagnostic, Pre-Programmed, Single-Function
	§870.1915, II	KRB	Probe, Thermodilution
	§870.2060, II	DRQ	Amplifier and Signal Conditioner, Transducer Signal
	§870.2300, II	DRT	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm)
	§870.2340, II	DPS	Electrocardiograph
	§870.2340, II	MLC	Monitor, ST Segment
	§870.2350, II	DRW	Electrocardiograph, Lead Switching Adapter
	§870.2370, II	KRC	Tester, Electrode, Surface, Electrocardiograph
	§870.2600, I	DRJ	System, Signal Isolation
	§870.2700, II	DQA	Oximeter
	§870.2770, II	DSB	Plethysmograph, Impedance

Device Panel	Classification	ProCode	Description
	§870.2800, II	DSH	Recorder, Magnetic tape, Medical
	§870.2810, I	DSF	Recorder, Paper Chart
	§870.2850, II	DRS	Extravascular Blood Pressure Transducer
	§870.2900, I	DSA	Cable, Transducer and Electrode, incl. Patient Connector
	-	MSX	System, Network and Communication, Physiological Monitors
	§870.2910, II	DRG	Transmitters and Receivers, Physiological Signal, Radiofrequency
Anesthesiology Devices	§868.1400, II	CCK	Analyzer, Gas, Carbon Dioxide, Gaseous-Phase
	§868.1500, II	CBQ	Analyzer, Gas, Enflurane, Gaseous-Phase (Anesthetic Concentration)
	§868.1500, II	NHO	Analyzer, Gas, Desflurane, Gaseous-Phase (Anesthetic Concentration)
	§868.1500, II	NHP	Analyzer, Gas, Sevoflurane, Gaseous-Phase (Anesthetic Concentration)
	§868.1500, II	NHQ	Analyzer, Gas, Isoflurane, Gaseous-Phase (Anesthetic Concentration)
	§868.1620, II	CBS	Analyzer, Gas, Halothane, Gaseous-Phase (Anesthetic Concentration)
	§868.1700, II	CBR	Analyzer, Gas, Nitrous Oxide, Gaseous-Phase (Anesthetic Concentration)
	§868.1720, II	CCL	Analyzer, Gas, Oxygen, Gaseous-Phase
	§868.1880, II	BZC	Data calculator Pulmonary-function
	§868.2375, II	BZQ	Monitor, Breathing Frequency
	§868.2480, II	LKD	Monitor, Carbon Dioxide, Cutaneous
	§868.2500, II	KLK	Monitor, Oxygen, Cutaneous, for Infant not under Gas Anesthesia
General Hospital and Personal Use Devices	§880.2910, II	FLL	Thermometer, Electronic, Clinical
Neurological	§882.1400, II	GWR	Electroencephalograph

Device Panel	Classification	ProCode	Description
Devices	§882.1420, I	GWS	Analyzer, Spectrum, Electroencephalogram Signal

3. The modified devices are substantially equivalent to previously cleared Philips IntelliVue Patient Monitors marketed pursuant to K021778, K030038, K032858, K033444, K033513, K040304, K040357, K041235, K042845, K050762, K051106, K052801, K053522, K060221, K060541, K061052, K061610, K062283, K063315, K062392, K063725, K071426, K072020, K081793, K082633, K083517, K091927, K093268, K100939

4. The Philips IntelliVue Patient Monitor family comprises the multi-parameter patient monitor models: MP2, X2, MP5, MP5T, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90 and MX800 IntelliVue Patient Monitors that consist of display units including built-in or separate flat panel displays and central processing units (CPU) and physiological measurement modules. All monitors share the same system architecture and exactly the same software is executed on each monitor.
   The IntelliVue Patient Monitors measure multiple physiological parameters such as surface ECG, invasive and non-invasive pressure, etc., generate alarms, record physiological signals, store derived data, and communicate derived data and alarms to central stations via the IntelliVue Clinical Network.
   The subject modification is the introduction of software revision H.03 for the entire IntelliVue Patient Monitors family.

5. The modified devices have the same intended use as the predicate devices. The Philips MP2, X2, MP5, MP5T, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90 and MX800 IntelliVue Patient Monitors are intended for monitoring and recording of and to generate alarms for, multiple physiological parameters of adults, pediatrics and neonates in hospital environments. The MP2, X2, MP5, MP20, MP30, MP40, and MP50 are additionally intended for use in transport situations within hospital environments. The MP2, X2, and MP5 are also intended for use during patient transport outside of a hospital environment. The monitors are not intended for home use. They are intended for use by health care professionals.

6. The modified devices have the same technological characteristics as the predicate device.

7. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the modified devices with respect to the predicate. Testing involved system level and regression tests as well as testing from the hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate devices and test results showed substantial equivalence. The results demonstrate that the Philips IntelliVue Patient Monitors meet all reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
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OCT 21 2010

Re: K102562
Trade/Device Name: Philips Medical Systems MP2, X2, MP5, MP5T, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90 and MX8000 IntelliVue Patient Monitors with Software Revisions H.03
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detection or alarms (including ST-segment measurement and alarm)
Regulatory Class: Class II
Product Code: MHX
Dated: September 3, 2010
Received: September 7, 2010

Dear Mr. Suchi:

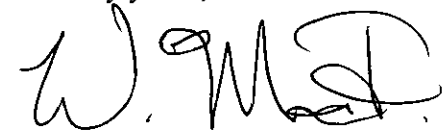
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

OCT 2 1 2010

510(k) Number (if known):_____

Device Name: Philips MP2, X2, MP5, MP5T, MP20, MP30, MP40, MP50, MP60, MP70, MP80, MP90 and MX800 IntelliVue Patient Monitors, Software Revision H.03.

Indications for Use: Indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients. Intended for monitoring and recording of and to generate alarms for multiple physiological parameters of adults, pediatrics and neonates in hospital environments. The MP2, X2, MP5, MP5T, MP20, MP30, MP40, and MP50 are additionally intended for use in transport situations within hospital environments. The MP2, X2 and MP5 are also intended for use during patient transport outside of a hospital environment.

Prescription Use (Part 21 CFR 801 Subpart D)	___yes__	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)	__No___

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102562